K052582

OCT 1 4 2005

Premarket Notification 510(k) Summary
As required by section 807.92
Datex-Ohmeda S/5™ Single-width Airway Module, E-MINIC and accessories

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

GE Healthcare
86 Pilgrim Road
Needham, MA 02492 USA
Tel: 781-449-8685
Fax: 781-433-1344

NAME OF CONTACT:

Mr. Joel Kent

DATE:

September 16, 2005

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

Datex-Ohmeda S/5™ Single-width Airway Module, E-MINIC and accessories

COMMON NAME:

Carbon dioxide gas monitor

CLASSIFICATION NAME:

The following Class II classification appears applicable:

Product Code	Classification Name	CFR Section
CCK	Analyzer, Gas, Carbon-Dioxide, Gaseous-phase	868.1400

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The Datex-Ohmeda S/5™ Single-width airway module, E-miniC is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda Single-width airway module, M-miniC (K023454).

DEVICE DESCRIPTION as required by 807.92(a)(4)

The Datex-Ohmeda E-miniC module is a single-width plug-in parameter module for a Datex-Ohmeda modular monitoring system. The Datex-Ohmeda S/5 E-miniC module can be used with the following Datex-Ohmeda modular monitors:

- S/5™ Anesthesia Monitor (AM) with main software L-ANE02(A)..00 (K021279) or newer version
- S/5™ Compact Anesthesia Monitor (CAM) with main software L-CANE02(A)..00 (K022485) or newer version.
- S/5™ Critical Care Monitor (CCM) with main software L-ICU02(A)..00 (K021376) or newer version
- S/5™ Compact Critical Care Monitor (CCCM) with main software L-CICU02(A)..00 (K022740) or newer version.

The E-miniC module uses mainly the same accessories as the predicate device, M-miniC (K023454). The main accessories include airway gas sampling lines, mini D-fend water traps and airway adapters. Some supplies have been discontinued, and the Exhaust line for gas return has been redesigned for a new gas return connector. The E-miniC module is a side stream gas analyzer for monitoring the Carbon dioxide (CO2) inhaled and exhaled by the patient by measuring absorbtion of CO2 at 4.2-4.3 mm using narrow band infrared filters/sensors. The E-miniC also allows monitoring of the respiration rate. The CO2 is measured and displayed breath by breath. The module is first plugged into the frame of the Monitor. The sampling line is attached to the module connector. The monitor is switched on and the gas sampling line is attached to the airway adapter. The airway adapter is attached between ventilator Y-piece and Heat and moisture exchanger (HME) of the patient's intubation tube. The monitor displays measurements from the E-miniC module in the form of numeric values, CO2 waveform and trends. The waveform size, color and sweep speed can be adjusted. The monitor also generates audible and visual alarms for this module and indicates the priorities and sources of alarms, according to the user interface for alarms in Datex-Ohmeda S/5 patient monitors.

INTENDED USE as required by 807.92(a)(5)

Intended Use:
The Datex-Ohmeda S/5 Single-width airway module, E-miniC is intended to be used with Datex-Ohmeda S/5 modular monitors; S/5 Anesthesia Monitor, S/5 Compact Anesthesia Monitor, S/5 Critical Care Monitor and S/5 Compact Critical Care Monitor for monitoring CO2 and respiration rate of all hospital patients.

Indications for use:
The Datex-Ohmeda S/5 Single-width airway module, E-miniC and accessories is indicated for monitoring CO2 and respiration rate of all hospital patients. E-miniC is indicated for monitoring patients weighing more than 5kg (11 lbs.).
The device is indicated for use by qualified medical personnel only.

SUMMARY OF TECHNOLOGICAL CHARACTERITICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The Datex-Ohmeda S/5™ Single-width airway module, E-miniC is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda Single-width airway module, M-miniC (K023454).

The E-miniC module has the following similarities compared to the predicate M- miniC (K023454):

- identical intended use and indications for use
- identical fundamental scientific technology
- use the same operating principle
- the same accessories (some supplies discontinued, one redesigned)
- have the same user interface at the monitor and alarms (can be used with the same monitor software)
- the Customer and parameter specifications are the same
- have the same safety and effectiveness
- are manufactured using the same processes

The main differences between the new E- miniC and the predicate M-miniC (K023454) is primarily due to fact that the new E- miniC module has the following changes:

- New color, shape, and size and thus differing mechanics
- The front panel and labeling have changed
- E-miniC uses the improved CO2 measuring miniC unit of the previously cleared S/5 FM Monitor (K043276)

Based on the analysis and other documentation included in this 510(k) notification and attachments it is evident that the main features and indications for use of the Datex-Ohmeda S/5™ Single-width airway Module, E-miniC and accessories are substantially equivalent to the predicate Datex-Ohmeda M- miniC Module (K023454).

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

The Datex-Ohmeda S/5™ Single-width airway Module, E-miniC and accessories has been assessed against the standards below. The device has been thoroughly tested through validation and verification of specifications.

- COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices
- FDA/DCRND Reviewer Guidance for Premarket Notification Submissions, November 1993
- IEC 60601-1:1988 + Amdt. 1:1991 + Amdt. 2:1995 (Part 1: General requirements for safety)
- EN 60601-1:1990+ A1:1993 + A13:1996 + A2:1995 (identical to IEC60601-1:1988 + Amdt. 1:1991 + Amdt. 2:1995)
- CAN/CSA C22.2 No. 601.1-M90 + S1:1994 (Canadian deviations to IEC 60601-1:1988 + Amdt. 1:1991) + S2:1998 (=IEC Amdt 2:1995)
- UL 2601-1, October 24, 1997 (U.S. deviations to IEC 60601-1:1988 + Amdt. 1:1991+ Amdt. 2:1995)
- IEC 60601-1-2:2001 (Electromagnetic compatibility – Requirements and tests)
- FDA/ODE Guidance for Content of Premarket Submission for Software Contained in Medical Devices. (May, 11, 2005)
- ISO 9918:1993 / EN 864:1996 Medical electrical equipment-Capnometers for use with humans-Particular requirements
- ASTM F-1456: 2001 Standard Specification for Capnometers

CONCLUSION:

The summary above shows that there are no new questions of safety and effectiveness for the Datex-Ohmeda S/5™ Single-width airway module, E-miniC as compared to the legally marketed (predicate) Datex-Ohmeda Single-width airway module, M-miniC (K023454).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 14 2005

Mr. Joel Kent
Manager, Quality and Regulatory Affairs
GE Healthcare
86 Pilgrim Road
Needham, Massachusettes 02492

Re: K052582
Trade/Device Name: DATEX-OHMEDA S/5 SINGLE-WIDTH AIRWAY MODULE, E-MINIC AND ACCESSORIES
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Monitor
Regulatory Class: II
Product Code: CCK
Dated: September 16, 2005
Received: September 20, 205

Dear Mr. Kent:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Datex-Ohmeda S/5 Single-width airway module, E-miniC and accessories.

Indications for use:

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Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Linda Y. Michaelis

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K052582